

### **REMARKS/ARGUMENTS**

As explained in further detail below, Applicants respectfully submit that independent Claims 1, 7, 24, and 37 are distinguishable from the cited references. In light of the subsequent remarks, which do not raise new issues, Applicants respectfully request reconsideration and allowance of the claims.

In the final Office Action, Claims 1, 3-8, 10-24, 37 39-42, 45, 48, 52, and 56 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,919,147 to Jain (“Jain”) in view of U.S. Patent No. 5,010,892 to Colvin et al. (“Colvin”), U.S. Patent No. 6,712,771 to Haddock et al. (“Haddock”), U.S. Patent No. 6,033,359 to Doi (“Doi”), and U.S. Patent No. 6,450,977 to Baxter-Jones (“Baxter-Jones”). Moreover, Claims 46, 49, 50, 53, 54, and 57 are rejected under 35 U.S.C. §103(a) over Jain in view of Colvin, Haddock, Doi, and Baxter-Jones and further in view of U.S. Patent No. 4,972,584 to Baumann (“Baumann”).

#### **Rejection under §112, ¶1**

The Examiner rejects Claims 5, 12, and 41 for allegedly failing to comply with the written description requirement because “the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit.” Applicant continues to disagree with the rejection, as Claims 5, 12, and 41 are supported by the specification. For example, page 10, lines 23-26 of the present application clearly states that “when the measurement assembly is retracted, the legs are relaxed and reside adjacent to one another so that the legs may be retracted within the exterior conduit” (emphasis added). Thus, the term “adjacent” was used to describe that the legs are in direct contact with one another.

The only difference between the embodiments shown in FIGS. 1-13 and FIGS. 14-18 is that the distal ends of the legs are coupled together in FIGS. 14-18, and the specification does not disclose otherwise. In fact, FIG. 4 (with the distal ends of the legs not coupled) and FIG. 15 (with the distal ends of the legs coupled) are practically identical, and the reference numbers used to identify the embodiment of FIGS. 14-18 are the same as the embodiment shown in FIGS.

1-13. In addition, FIG. 18 of the present application shows the legs displaced from the exterior conduit, wherein portions of the legs proximate to the proximal and distal ends are in flush contact, such that as the legs are retracted into the exterior conduit, the legs would lie flush with one another along their entire length. Clearly, the only difference between the embodiments is that the distal ends of the legs are either coupled or not coupled together. Therefore, Applicant respectfully submits that the rejection of Claims 5, 12, and 41 under §112, ¶1, is overcome.

Rejection under §103(a)

In Applicant's previous response, independent Claims 1, 7, 24, and 37 were amended to recite that the exterior conduit is configured to engage the measurement markers of the legs in order to provide an indication of a diameter of the target segment. Despite Applicants' amendments and arguments, the Examiner continues to believe that a combination of Jain, Doi, and Baxter-Jones discloses such a configuration, wherein Doi discloses a length-measuring tool that includes strips having a scale that are configured to spread outwardly via bendable portions and provide information regarding the size of a diseased part, and Baxter-Jones discloses a slidable indicator that includes a measuring scale for determining the length of a female reproductive organ.

Applicants respectfully disagree with the rejection of Claims 1, 7, 24, and 31, as none of the cited references, taken alone or in combination, teaches or suggests an exterior conduit configured to engage the measurement markers of the legs in order to provide an indication of a diameter of the target segment. In particular, Applicants submit that there is no motivation to modify Jain or any of the cited references to include an exterior conduit that is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment. In this regard, in order to properly combine references, a teaching or motivation to combine the references is essential. *In re Fine*, 337 F.2d 1071, 1075 (Fed. Cir. 1988). In fact, the Court of Appeals for the Federal Circuit has stated that, "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability -- the essence of hindsight." *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). Although the evidence of a

suggestion, teaching, or motivation to combine the references commonly comes from the prior art references themselves, the suggestion, teaching, or motivation can come from the knowledge of one of ordinary skill in the art or the nature of the problem to be solved. *Id.* In any event, the showing must be clear and particular and “[b]road conclusory statements regarding the teaching effect of multiple references, standing alone, are not ‘evidence.’” *Id.* Although the Court in *KSR Int’l Co. v. Teleflex Inc.* found that the teaching, suggestion, and motivation test should not be rigidly applied, some teaching, suggestion, or motivation and a reasonable expectation of success are needed in order to properly combine references. *See* MPEP §2143 (citing *KSR*, 550 U.S. \_\_\_, 82 USPQ2d, 1385 (2007)).

The Examiner contends that Doi discloses measurement markers (8) on the lumen facing surface of the legs (3) and that Baxter-Jones discloses an exterior conduit (1116) that is configured to engage measurement markers or detents (1130) of the legs to provide an indication of a diameter of the target segment. However, the scales or alleged measurement markers of Doi are not configured to bend or otherwise engage an endoscope but, rather, are painted on the outer surface of each strip so that the scales are disposed within a visual field that is viewable with an observation optical system of the endoscope (see Doi, col. 3, lines 12-14 and 49-53). In addition, the measurement indicators on the outer surface of the strips of Doi are functionally unrelated to the slidable indicator of Baxter-Jones. In particular, if the device of Doi was modified to include the slidable indicator of Baxter-Jones or an exterior conduit for engaging the scales, the scales would not be within the field of view of the endoscope, and the ability of the strips to flex about the bendable portions and form the disclosed X-shape would also be affected. Moreover, even if one were to modify Jain to include the measurement indicators of Doi, the measurement indicators are not configured to engage the exterior conduit. And, Baxter-Jones does not disclose legs at all such that there is no teaching or suggestion to modify Jain to include detents on the outer surface of the filaments given that the detents of Baxter-Jones are configured to engage a slidable indicator that slides over a single elongated member. And, there is simply no motivation to combine the references based on the fact that the device of Jain is used to measure a diameter of a target segment and the device of Baxter-Jones is employed to measure the length of a cervix. These references are used for entirely different purposes and function in entirely different

manners such that one of ordinary skill in the art would not have been motivated to modify either reference in light of one another. Thus, the Examiner is simply picking and choosing elements from each of the cited references and is using impermissible hindsight to arrive at the claimed invention. Therefore, there is no motivation or suggestion to modify Jain in light of any of the remaining cited references to include an exterior conduit that is configured to engage legs having measurement indicators on their lumen-facing surfaces in order to determine a diameter of a target segment, as recited by independent Claims 1, 7, 24, and 31.

In view of the remarks and amendments presented above, it is respectfully submitted that Claims 1, 3-8, 10-24, 37, 39-42, 45, 46, 48-50, 52-54, 56, and 57 of the present application are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

Although Applicants submit that each of the dependent claims are allowable for at least those reasons discussed above for a respective independent claim, Applicants submit that several of the dependent claims are further distinguishable from the cited references. For example, none of the cited references teaches or suggests dependent Claims 45, 46, 48-50, 52-54, 56, and 57, which are directed to engagement of a lip on the exterior conduit with detents on the legs.

In order to overcome Jain's shortcomings, the Examiner relies on Baxter-Jones as disclosing Claims 45, 48, 52, and 56, which recite that the measurement markers of the legs comprise detents defined therein. However, as described above, there is no teaching or suggestion to modify Jain in view of Baxter-Jones and/or Doi to include measurement markers defined on the lumen facing surfaces of the legs, let alone detents, that are configured to engage the outer conduit to provide an indication regarding a diameter of a target segment. Therefore, none of the cited references, taken alone or in combination, teaches or suggests Claims 45, 48, 52, and 56.

With respect to 46, 49, 50, 53, 54, and 57, Applicants submit that Baumann is non-analogous art for purposes of an obviousness rejection under 35 U.S.C. § 103(a). In particular, "Any analogous or pertinent prior art plays a role in the determination of the patentability of the claims at the time of invention." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 726 (Fed.

Cir. 2002). A prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992).

In this vein, Baumann is directed to a haircutting and trimming device that is clearly non-analogous and not pertinent to one of ordinary skill in the art for measuring a lumen or any other target segment within a patient. Haircutting and trimming devices are not "reasonably pertinent" to solving the problem of measuring the lumen or a target segment of a patient. Although Baumann discloses that the device may be adjusted to vary the length of hair that is cut, there is simply no reason why this particular feature would be applicable to devices that are used in the human body. Baumann is not even used to measure the length of the hair but, instead, provides a means to incrementally adjust the length of hair being cut such that there is not even the pertinence of obtaining a measurement. Applicants fail to appreciate the relevance of "cutlery" devices to medical devices used to determine a measurement within the human body and submit that Baumann is non-analogous art and should not be relied upon as prior art against the claimed invention.

In any event, even if Baumann is erroneously combined with Jain and the remaining cited references, Applicants respectfully disagree with that there is any teaching or suggestion to modify any of the cited references in light of Baumann to render Claims 46, 49, 50, 53, 54, and 57 obvious. Claims 46, 49, 53, and 57 recite that the exterior conduit comprises inner and outer surfaces, wherein the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. Claims 50 and 54 recite that the method further includes measuring a diameter of the lumen by displacing the exterior conduit and measurement assembly relative to one another such that the lip engages a detent defined in each of the legs. The Examiner acknowledges that "Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones do not teach that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents." Instead, the Examiner relies on Baumann as teaching this particular configuration. However, the Examiner appears to contradict a previous statement regarding Claims 45, 48, 52, and 56, wherein Baxter-Jones was relied upon as disclosing "a lip that extends from the distal end of an

exterior conduit (1116) to engage detents (1130) defined in an elongated measurement member (1108).” Therefore, Applicants request clarification regarding these contradicting statements.

Applicants submit that Baumann does not teach or suggest that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. In particular, Baumann does not disclose that the inner surface of the wall (54) includes a lip extending from its inner surface. Rather, the detent lever (52) is clearly pivotally attached to the outer surface of the wall about pivot (53). The Examiner finds that secondary air guide (46) is a “lip”, but the this guide is used to change the direction of the airstream (28) and in no way engages the notches (49). Therefore, neither Baumann, nor any of the remaining cited references, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

Furthermore, Applicants respectfully submit that there is no motivation to modify Jain in light of Baumann to include legs having detents defined on their lumen facing surfaces and a lip extending from an inner surface of an exterior conduit that engages the detents. In this regard, Baumann does not disclose measurement markers at all, let alone measurement markers used to provide an indication regarding a diameter of a target segment. To the extent the Examiner relies on Doi and/or Baxter-Jones for Baumann’s shortcomings, Applicants submit that there is clearly no suggestion to do so given that Baumann is in no way related to obtaining measurements. Therefore, Applicants respectfully submit that none of the cited references, taken alone or in combination, teaches or suggests Claims 46, 49, 50, 53, 54, and 57.

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### CONCLUSION

In view of the remarks presented above, which do not raise new issues, it is respectfully submitted that all of the present claims of the present application are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



Trent A. Kirk  
Registration No. 54,223

**Customer No. 37305**  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Charlotte Office (704) 444-1000  
Fax Charlotte Office (704) 444-1111

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